

CLAIMS

What is claimed as the invention is:

5 <sup>53</sup> 1. A method of conducting a clinical trial of a test  
substance over the internet from a primary site, comprising the  
following steps:

10 providing to at least one clinical trial participant  
located at a remote internet site distinct from the  
primary site, instructions on: using the test substance;  
accessing and completing at least one evaluation form from  
a website maintained at the primary site; and returning  
electronically said at least one evaluation form to the  
primary site;

15 providing said at least one evaluation form in  
electronic format for use by the participant, said at  
least one evaluation form having a question and answer  
section that, when completed by a participant using the  
test substance, provides information from which a  
20 determination can be made of one or more effects of the  
test substance on the participant completing the  
evaluation form; and

25 compiling data regarding at least one said effect of  
the test substance on the participant from information  
from a received and completed evaluation form returned by  
the participant to at least one investigator conducting  
the clinical trial.

30 2. The method of claim 1, further comprising obtaining  
informed consent from the participant to participate in the  
clinical trial.

3. The method of claim 2, wherein obtaining the participant's informed consent comprises sending a blank consent form from the primary site to the remote site, and receiving at the primary site from the remote site, a completed consent form from the participant to participate in the clinical trial.

4. The method of claim 2, wherein obtaining the participant's informed consent comprises:

causing a consent form to appear at the remote site, said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial, and

providing for authentication of the consent form.

5. The method of claim 4, wherein a computer server at the primary site causes the consent form to appear at the remote site computer in response to the primary site receiving from the remote-site, either a request for the consent form or a completed screening questionnaire,

said questionnaire having portions for receiving information for use in making a determination of whether an individual upon whose behalf the questionnaire is answered, is eligible to be a participant in the clinical trial.

6. The method of claim 2, wherein obtaining the participant's informed consent comprises sending a hardcopy

consent form to the participant for completion and return to at least one investigator conducting the clinical trial,

said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the candidate's medical information to at least one investigator conducting the clinical trial.

7. The method of claim 1, further comprising screening potential candidates over the internet for eligibility to participate in the clinical trial, the screening comprising:

- maintaining, at the primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination of whether a candidate is eligible to be a participant in the clinical trial;

- receiving the completed questionnaire at the primary site via the internet; and

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria.

8. A method of conducting a clinical trial of a test substance over the internet, comprising the following steps:

- maintaining, at a primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site from the remote site, of a request to display the questionnaire, wherein the questionnaire has portions for receiving information that enables a determination of whether a candidate, upon whose behalf the questionnaire is completed, is eligible to be a participant in the clinical trial;

- obtaining the candidate's informed consent to participate in the clinical trial;

- receiving the candidate's completed questionnaire at the primary site via the internet;

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria;

- after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate;

- providing to at least one clinical trial participant located at a remote internet site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website

maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

- providing said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

- compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

9. The method of claim 7 or 8, further comprising causing information transfer between the primary site and remote site for the purpose of confirming the existence, identity, and eligibility of the participant.

10. The method of claim 7 or 8, wherein the confirming is accomplished by performing at least one step selected from the group consisting of: interviewing the participant by telephone or in person; reviewing at least one medical record of the participant; interviewing a health care professional who has provided health care to the participant; and reviewing at least one communication from the health care professional to the at least one investigator regarding the health status of the participant.

11. The method of claim 7 or 8, wherein the eligibility of the participant to participate in the clinical trial is determined by comparing the participant's answers to the

questionnaire with a reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested.

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12. The method of claim 1, 2, 7 or 8, further comprising, prior to compiling data regarding the at least one effect, causing delivery, under authority of the investigator, of the test substance to the participant.

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~~13. The method of claim 1, 2, 7, or 8, further comprising collecting and storing at a secure site accessible by the at least one investigator and by the participant upon providing a log-in password, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.~~

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14. The method of claim 13, wherein the secure site is the primary site.

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~~15. The method of claim 1, 2, 7, or 8, further comprising assigning to the participant, a unique identifier and a unique log-in password for accessing protected information from the primary site.~~

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16. The method of claim 1, 2, 7, or 8, further comprising monitoring at least one effect of the test substance on the participant by reviewing a plurality of evaluation forms each completed and returned by the participant to at least one

investigator, wherein each of the multiple evaluation forms is provided electronically to the participant at predetermined different times after the participant has commenced using the test substance.

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17. The method of claim 16, repeated with multiple participants in the clinical trial.

18. The method of claim 1, 2, 7, or 8, repeated with multiple participants, and further comprising: assigning to each participant, a unique identifier and a unique log-in password for accessing protected information stored at the primary site; and collecting and analyzing data generated by the multiple participants each completing and returning the at least one evaluation form to the at least one investigator.

~~19. The method of claim 18, further comprising assigning a unique identifier and a unique log-in password to each participant for accessing protected information from the primary site.~~

20. The method of claim 1, 2, 7, or 8, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

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21. The method of claim 16, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

22. The method of claim 18, further comprising providing encryption for information transmitted between the primary site and the remote site via the internet.

5        23. The method of claim 1, 2, 7, or 8, wherein the determination of the at least one effect comprises comparing answers from at least one evaluation form completed by the participant after having used the test substance, with answers from at least one evaluation form completed by the participant  
10 prior to using the test substance.

24. The method of claim 17, further determining, from the data compiled from received and completed evaluation forms from multiple participants, whether the test substance has clinical  
15 efficacy in treating a predetermined medical condition.

25. The method of claim 18, further determining, from the data compiled from received and completed evaluation forms from multiple participants, whether the test substance has clinical  
20 efficacy in treating a predetermined medical condition.

26. The method of claim 24, wherein determining the test substance's clinical efficacy comprises comparing the compiled data from participants using the test substance with data  
25 compiled from information from received and completed evaluation forms returned to at least one investigator by participants using a placebo.

27. The method of claim 25, wherein determining the test  
30 substance's clinical efficacy comprises comparing the compiled data from participants using the test substance with data



compiled from information from received and completed evaluation forms returned to at least one investigator by participants using a placebo.

5           28. A computer-readable medium carrying a computer program that is operable in the method of claim 1, 3, 4, 5, 7, or 8.

10           29. A system for conducting a clinical trial of a test substance over the internet from a primary site, comprising at least one computer at the primary site that comprises:

15           program code for providing, via the internet, to at least one clinical trial participant located at a remote site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

20           program code for providing said at least one evaluation form in electronic format for use by the participant at the remote site, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

25           program code for compiling into a central database at the primary site, data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

30. The system of claim 29, further comprising program code for causing a consent form to appear at the remote site, said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial.

31. The system of claim 30, further comprising means for receiving and electronically authenticating a consent form completed and returned via the internet by the clinical trial participant.

32. The system of claim 29, further comprising means for screening potential candidates over the internet for eligibility to participate in the clinical trial, including:

- means for maintaining, at the primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

- means for causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination of whether a candidate is eligible to be a participant in the clinical trial; and

- means for receiving the completed questionnaire at the primary site via the internet.

33. The system of claim 32, further comprising means for reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria.

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34. The system of claim 33, wherein the reviewing and determining means provides for comparing the participant's answers to the questionnaire with a reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested.

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35. the system of claim 33, further comprising means for informing the candidate, via the internet, of the candidate's eligibility to participate in the clinical trial.

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36. The system of claim 32, further comprising means for causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate.

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37. The system of claim 29, 31, 32, 35, and 36, further comprising a means for encrypting information transferred between the primary site and the remote site.

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38. The system of any of claims 29-36, further comprising means for collecting and storing at a secure site accessible by the at least one investigator and by the participant upon providing a log-in password, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one

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investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.